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| EXAMINER |
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LANDAU, SHARMILA GOLLAMUDI

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1611

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/743,577         | <b>Applicant(s)</b><br>SCHLACHTER, HERBERT |  |
|                              | <b>Examiner</b><br>Sharmila Gollamudi Landau | <b>Art Unit</b><br>1611                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-13, 17-19 and 22-43 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-13, 17-19, and 22-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/8/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Receipt for Amendments/Remarks and IDS filed on 2/19/08 is acknowledged. Claims 2-13, 17-19 and 22-43 are pending in this application. Claims 1, 14-16, 20-21, and 44 stand cancelled. Claims 41-43 are withdrawn as being directed to a non-elected invention. Claims 2-13, 17-19, and 22-40 are directed to the elected species.

### ***Election/Restrictions***

Applicant's election with traverse of species polyphenols and cellulitis in the reply filed on 2/19/08 is acknowledged. Applicant's arguments are unclear. It is unclear if applicant is arguing that the species are obvious variants. Meaning all the secondary plant substances are obvious variants and all the disorders listed including microcirculation, herpes, and cancer are obvious variants. If applicant is arguing that these species are obvious variants, then applicant must clearly state this on record. Upon doing so, the examiner will withdraw the requirement.

It is further noted that on page 11 of the traversal, applicant acknowledges that the " the proper approach in this instance is for the Examiner to require an election of species for initial examination and then, if elected species is found patentable, the Examiner should move on to examine additional species to determine if a generic claim is allowable. Applicant requests that the Examiner undertake this proper approach." It should be noted that this approach has been taken and as clearly acknowledged by applicant on page 11, it is proper.

The requirement is still deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

The information disclosure statement filed 8/8/07 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because: The English translation of the NPL document

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submitted to rebut the examiner's rejection must be certified. The examiner is not requesting that all 250 pages must be certified. However, the pertinent pages which applicant relies on must be certified to be considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 40 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, hematomas, hemorrhoids, does not reasonably provide enablement for treating skin cancer and herpes is withdrawn in light of the amendments filed 2/19/08.

***Response to Arguments to Prior Art***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, since the examiner has retained Oliver et al, the examiner will address applicant arguments pertaining to Oliver, EP '812, Horrobin, and Burke.

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Applicant argues Oliver does not teach a secondary plant substance and plant extract do not automatically contain secondary plant substances. The examiner respectfully disagrees. Oliver teaches the use of witch hazel, Echinacea, golden seal, garlic, red clover, and tea tree. All of these are secondary plant substances. Applicant has elected polyphenols. Witch hazel, Echinacea, golden seal, garlic, and red clover all contain polyphenols. Note the references cited as evidence.

Applicant argues that although Oliver teaches the use tea tree oil, Oliver does not disclose which components in the oil have the desired effect. Applicant argues that Rompp Lexikon discloses that tea tree oil can contains up to 40% terpineen-4-ol and thus 60% comprises non-terpene compounds.

It is noted that applicant has not provided the reference which purportedly teaches that tea tree contains 60% non-terpene compounds. The examiner however does cite US Pharmacist as evidence that tea tree oil comprises beta-pinene, p-cymene, limonene, aromadendrene, 1-8 cineole, along with terpineen-4-ol. Beta-pinene, p-cymene, limonene, aromadendrene, and 1-8 cineole, are all terpenes. Thus, the examiner disagrees with applicant's assertion that tea tree oil contains 60% non-terpene compounds since the other components in tea tree oil (beta-pinene, p-cymene, limonene, aromadendrene, and 1-8 cineole) are terpenes. The examiner further notes that page 8, third paragraph, of the instant specification states that the secondary plant substances can be used in its natural forms.

Applicant argues “that Oliver even suggests the use of SPS can only be made based on hindsight reconstruction using the knowledge disclosed by the present invention.”

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Applicant's arguments pertaining to the SPS are perplexing since clearly Oliver discloses the use of natural plant substances as discussed above. Further, it is unclear how the fact that the garlic, red clover, golden seal, Echinacea, and tea tree inherently contain applicant's claimed SPS is construed as hindsight. This is not hindsight but rather a fact.

Applicant argues that Oliver does not teach organic peroxides. The examiner respectfully disagrees. Oliver teaches hydrogen peroxide, which is an inorganic peroxide. For instance, US 4708880 discloses, "inorganic peroxides such as hydrogen peroxide". See column 2, line 19. The fact that Oliver only teaches, "peroxide may also be added to the inventive formulation in an amount between about 3 and 8 percent. Suitable peroxides include hydrogen peroxide. The purpose of including a peroxide component is to help treat any infection. The peroxide *may also* be selected from benzoyl peroxide, acetyl peroxide, t-butyl peroxide, para chlorobenzoyl peroxide, and methyl ethyl ketone peroxide." The use of "may also" is implicit that hydrogen peroxide is preferable. However, assuming arguendo that Oliver teaches a preference for organic peroxides, the examiner points out that "disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In instant case, the rejection is made under obviousness and the inorganic peroxide need only be *suggested*.

Applicant argues that EP '812 teaches that if benzoyl peroxide is used, the reference suggests a stronger anti-inflammatory agent such as hydrocortisone or NSAID.

The examiner notes the cited passage and also notes that EP '812 teaches that it can be used. Meaning that it is not mandatory and thus this is not a teaching away. This does not

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substantiate applicant's argument that the combined references are inoperable and applicant has not provided any evidence to support such an assertion.

Applicant argues Horrobin does not teach zinc oxide, an inorganic peroxide, and an amino acid.

The examiner points out that the instant claims are rejected under obviousness. The test for obviousness is not whether the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the examiner relies on Horrobin to cure the deficiencies of Oliver. Horrobin is specifically relied on to teach the use of polyunsaturated fatty acids and amino acids. Further, it is noted applicant attacks the references individually whereas the reject is based on a combination of references. Applicant has not addressed the examiner's motivation.

Applicant argues that that Horrobin teaches a multiplicity of compounds that could be used for increasing the level of E-series prostaglandins. Applicant argues that Horrobin does not teach any preference for rutin or bioflavonoids. Applicant argues that since Horrobin does not teach an inorganic peroxide in the composition and thus the compounds "may" not work.

First, it is pointed out that Horrobin teaches the function of each compound and the motivation to utilize each compound as set forth in the rejection. Further, it is noted that example 12 comprises rutin, lysine, a zinc salt, and lysine in one composition. Therefore, Horrobin not only teaches the function of all the compounds listed but incorporates the compounds into the composition. The very fact that all these compounds are utilized in the working examples is implicit that the combination is preferred. Second, it is noted that applicant makes assertions

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(that the compounds of Horrobin may not work with an inorganic peroxide) without any evidence to support such assertions. It is pointed out that Oliver suggests the combination of peroxides such as hydrogen peroxide, zinc compounds, aloe-vera (inherently contains amino acids) and Echinacea (inherently contains rutin). Thus, this is an indication that the compounds taught by Horrobin are not adversely effected by peroxides as purported by applicant.

Applicant argues that Horrobin teaches the use of glutathione and teaches away from rutin. Applicant argues that there is no motivation to add rutin to Oliver.

Again, it is noted that applicant attacks the references individually, when the rejection is based on a combination of references. Clearly applicant has not considered the rejection as a whole. The examiner disagrees that Horrobin teaches that if glutathione is used, then rutin cannot be used. Example 12 is evidence that both rutin and glutathione can be used in one composition. The examiner further points out that the primary reference is not deficient in the teaching of a secondary plant substance. As discussed above, Oliver teaches the use of Echinacea, garlic, red clover, tea tree oil, and golden seal. The fact that Horrobin teaches rutin also helps in treating skin disorders demonstrates that these compounds are known in the art, the compounds are routinely used for treating the skin, and it is known to combine all of these compounds in one composition. MPEP 2143.02 should be noted: "A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. KSR International Co. v. Teleflex Inc., 550



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U.S. 82 USPQ2d 1385, 1395 (2007)” In instant case, the rationale has clearly been laid out and applicant has not provided any persuasive unexpected results to overcome the rejection.

Applicant argues that lysine is not used in the examples. The examiner directs applicant’s attention to Example 12, 13, 14, 20, 18, 19, and 24.

Applicant argues Burke is directed to a cleanser. Applicant argues that Burke does not teach an amino acid, at least one secondary plant substance, zinc oxide, and an inorganic peroxide. Again, the examiner points out that Burke is not relied to teach a plant substance, zinc oxide, an inorganic peroxide, or an amino acid since the combination of Oliver and EP ‘812 or Horrobin, respectively, is not deficient in this sense. Burke is only relied upon to teach the functional equivalency of the claimed peroxides and Oliver’s hydrogen peroxide. Applicant has not addressed the examiner’s motivation or provided any unexpected results to overcome this rejection.

With regard to the fact that Burke teaches a cleanser and is non-analogous, the examiner it has been held that a prior art reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In instant case, Oliver teaches the use of hydrogen peroxide to treat infection of the skin. The examiner points out that Burke teaches hydrogen peroxide, zinc peroxide, sodium peroxide all function to disinfect the skin. Thus, both references are in the same field of endeavor and Burke teaches the same pertinent problem discussed by Oliver.

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Applicant argues that the examiner has not provided any motivation for the combining the references. The examiner disagrees and requests applicant look at the rejection carefully. Clearly a motivation has been provided for every rejection.

The examiner thanks applicant's reminder of hindsight reconstruction. However, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case and as discussed above, the prior art clearly teaches the function of all the claimed compounds, the prior art teaches a motivation to use each claimed compounds, and the prior art teaches the use of the compounds for the same purpose.

Regarding applicant's arguments pertaining to enablement, the examiner reminds applicant that such assertions should be factually supported. Applicant's attention is directed to MPEP 2143.02 II: Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)" Applicant has not submitted such evidence. However, the examiner has provided some reasonable expectation of success.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 2, 5-11, 17-19, 26-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (5,869,062) in view of EP 0281812 in further view of De Paoli (6,147,054) as evidenced by Hwang et al (Antimicrobial constituents from goldenseal (the Rhizomes of *Hydrastis canadensis*) against selected oral pathogens, *Planta Med.* 2003 Jul; 69(7):623-7); Wikipedia-Echinacea; Wikipedia-Witch Hazel; and [http://www.globalherbalsupplies.com/herb\\_information/aloe\\_vera.htm](http://www.globalherbalsupplies.com/herb_information/aloe_vera.htm).**

Oliver teaches a skin treatment composition for skin-related problems especially infection, acne and blemishes. See column 1, lines 4-11 and claims. The composition comprises 8-20% calamine (zinc oxide with 0.5% ferric oxide); 0.05-3% antioxidant; and 0.25-4% of an anti-bacterial. The naturally occurring anti-bacterial includes golden seal extract, tea tree oil

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(contains terpenes), Echinacea (contains polyphenols), garlic (contains polyphenols), and red clover (contains polyphenols). The composition further includes a peroxide component such as hydrogen peroxide. See column 1, lines 35-50 and column 3, lines 9-10. Oliver teaches calamine reduces inflammation, redness and itching, as well as for drying out excess oils and fluids. See column 2, lines 14-20. The second critical component is at least one anti-oxidant, which prevents free radical damage, such as vitamin C (ascorbic acid between 0.45 and 2 weight percent), vitamin E (between 0.08 and 1.0 weight percent), and beta-carotene (vitamin A). See column 2, lines 20-30. Oliver teaches the additional use of an astringent such as witch hazel and alpha hydroxy acids. The preferred astringent is witch hazel (contains tannins which are polyphenols) and the preferred range of the astringent is in an amount between about 1 and 12 %. See column 2, lines 57-65. The golden seal extract itself includes albumin, berberine, biotin, calcium, candine, chlorine, choline, chologenic acid, fat, hydrastine, inositol, iron, lignini manganese, volatile and essential oils, PABA, phosphorus, potassium, resin, starch, sugar, B complex and vitamins and acts to fight infections. See column 2, lines 40-47. Oliver teaches the use of peroxide in an amount between about 3 and 8%, which helps to treat any infection. Zinc oxide in the amount of 8-20% also is taught as an additional base. Aloe vera may be included in the amount of 0.01-0.05% for severe skin problems. It should be noted that aloe vera contains amino acids, vitamins C and E, zinc, fatty acids, minerals, etc. Note

[http://www.globalherbalsupplies.com/herb\\_information/aloe\\_vera.htm](http://www.globalherbalsupplies.com/herb_information/aloe_vera.htm) as evidence.

Oliver teaches a composition water, 20% glycerin (humectant), 18% calamine (ferric oxide and 0.5% zinc oxide), 18% zinc oxide, 5% witch hazel (flavonoids-polyphenols), 0.88%

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ascorbic acid, 5% EDTH, 5% peroxide, 2% golden seal (flavonoids-polyphenols), 0.70% tea tree oil (terpenes), and 0.16% vitamin E.

Oliver does not teach an amino acid in the composition. Further, although Oliver teaches the use of an antibacterial compound including natural plants extracts that contain polyphenols, the amount of polyphenols in the extract is unclear.

EP 0281812 teaches a composition for the treatment of acne comprising a keratolytic agent, an astringent such as zinc oxide, and an anti-inflammatory agent such as amino acids. EP '812 teaches amino acids are known to have anti-inflammatory activity and include cysteine, L-tryptophan, valine, alanine, glycine, glutamine, and aspartic acid in 2-30%. See column 5, lines 45-50. In the preferred embodiment, the acne treating composition comprising salicylic acid, zinc oxide, and cysteine. See column 6, lines 30-34.

Di Paoli teach a composition that is applied to intact or injured skin. See column 1, lines 5-20. The composition comprises vitamins in the amount of 0.01-10%, amino acids (alanine arginine, aspartic acid, asparagine, cysteine, glutamic acid, glutamine, glycine, histidine, leucine, isoleucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, or valine) in the amount of .001-20%; chemical substances from plants, including triterpenes, saponins, isoflavonoids, alcohol flavonoids including anthocyanidins (flavonoids-polyphenols). The anthocyanidins include quercitin, isoquercitin, echinacosides (from Echinacea), and echinacin in the amount of 0.01-20%, the plant extract itself including echinacia, witch hazel, and combinations, in the amount of 0.01-30% or 0.25-20%. See column 4, line 30-65 to column 5, line 5. The composition is used to treat acne, increase circulation, dermatitides, heal wounds, etc. see column 5, lines 20-35.

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First, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oliver and EP '812. One would have been motivated to further utilize amino acids in Oliver's composition to provide an additive anti-inflammatory activity to treat skin disorders such as acne. Further, a skilled artisan would have been motivated to combine the teaching with a reasonable expectation of success since both references teach the treatment of acne. Therefore, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Second, as evidenced by Hwang et al and Wikipedia, Goldenseal, Witch Hazel, and Echinacea all contain polyphenols including flavonoids (rutin, quercetin, echinacosides). Note that flavonoids are species within the genus polyphenols. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Di Paoli and utilize either the natural plant extract or the chemical active in the plant extracts such as flavonoids, to treat skin conditions such as acne. Thus, it is within the skill to utilize the plant extract or the active chemical constituent itself in the instant amount to treat skin conditions. Further Di Paoli teaches the use of the plant extract or the active chemical constituents in the instant amount wherein this amount overlaps the amount taught by Oliver. Therefore, it is within the skill of an artisan to manipulate the concentration to achieve the optimal benefit.

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Regarding the recitation at least one trace element, note that calamine contains ferric oxide.

Regarding the recitation at least one vitamin, Oliver teaches the incorporation of vitamins and Vitamin E is used in the composition.

Regarding the recitation at least humectant, Oliver's composition comprises glycerin.

Regarding the recitation at least one antifungal or antimicrobial components, Oliver teaches the incorporation of tea tree oil.

**Claims 2-11, 13, 17-19, 22-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (5,869,062) in view of Horrobin (5,145,686) in further view of De Paoli (6,147,054) as evidenced by Hwang et al (Antimicrobial constituents from goldenseal (the Rhizomes of *Hydrastis canadensis*) against selected oral pathogens, *Planta Med.* 2003 Jul; 69(7):623-7); Wikipedia-Echinacea; Wikipedia-Witch Hazel; and [http://www.globalherbalsupplies.com/herb\\_information/aloe\\_vera.htm](http://www.globalherbalsupplies.com/herb_information/aloe_vera.htm).**

Oliver teaches a skin treatment composition for skin-related rashes, skin bites, razor irritation, chicken pox, athlete's foot, general itching, and infections, and acne. See column 1, lines 4-11 and claims. The composition comprises 8-20% calamine (zinc oxide with 0.5% ferric oxide); 0.05-3% antioxidant; and 0.25-4% of an anti-bacterial. The naturally occurring anti-bacterial includes golden seal extract, tea tree oil (contains terpenes), Echinacea (contains polyphenols), garlic (contains polyphenols), and red clover (contains polyphenols). The composition further includes a peroxide component such as hydrogen peroxide. See column 1, lines 35-50 and column 3, lines 9-10. Oliver teaches calamine reduces inflammation, redness and itching, as well as for drying out excess oils and fluids. See column 2, lines 14-20. The second

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critical component is at least one anti-oxidant, which prevents free radical damage, such as vitamin C (ascorbic acid between 0.45 and 2 weight percent), vitamin E (between 0.08 and 1.0 weight percent), and beta-carotene (vitamin A). See column 2, lines 20-30. Oliver teaches the additional use of an astringent such as witch hazel and alpha hydroxy acids. The preferred astringent is witch hazel (contains tannins which are polyphenols) and the preferred range of the astringent is in an amount between about 1 and 12 %. See column 2, lines 57-65. The golden seal extract itself includes albumin, berberine, biotin, calcium, candine, chlorine, choline, chologenic acid, fat, hydrastine, inositol, iron, lignini manganese, volatile and essential oils, PABA, phosphorus, potassium, resin, starch, sugar, B complex and vitamins and acts to fight infections. See column 2, lines 40-47. Oliver teaches the use of peroxide in an amount between about 3 and 8%, which helps to treat any infection. Zinc oxide in the amount of 8-20% also is taught as an additional base. Aloe vera may be included in the amount of 0.01-0.05% for severe skin problems. It should be noted that aloe vera contains amino acids, vitamins C and E, zinc, fatty acids, minerals, etc. Note

[http://www.globalherbalsupplies.com/herb\\_information/aloe\\_vera.htm](http://www.globalherbalsupplies.com/herb_information/aloe_vera.htm) as evidence.

The composition comprises 8-20% calamine (zinc oxide with 0.5% ferric oxide); 0.05-3% antioxidant; and 0.25-4% of an anti-bacterial. The composition further includes one or more astringents and a peroxide component such as hydrogen peroxide. See column 1, lines 35-50 and column 3, lines 9-10. Oliver teaches calamine reduces inflammation, redness and itching, as well as for drying out excess oils and fluids. See column 2, lines 14-20. The second critical component is at least one anti-oxidant, which prevents free radical damage. Such as vitamin C (ascorbic acid between 0.45 and 2 weight percent), vitamin E (between 0.08 and 1.0 weight



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percent), and beta-carotene (vitamin A). See column 2, lines 20-30. The naturally occurring anti-bacterial includes 0.35-0.95% golden seal extract, 1-3% tea tree oil (contains terpenes), echinacea, garlic, and red clover. Oliver teaches the additional use of an astringent such as witch hazel and alpha hydroxy acids. The preferred astringent is witch hazel and the preferred range of the astringent is in an amount between about 1 and 12 %. See column 2, lines 57-65. The golden seal extract itself includes albumin, berberine, biotin, calcium, candine, chlorine, choline, chologenic acid, fat, hydrastine, inositol, iron, lignini manganese, volatile and essential oils, PABA, phosphorus, potassium, resin, starch, sugar, B complex and vitamins and acts to fight infections. See column 2, lines 40-47. Oliver teaches the use of a peroxide in an amount between about 3 and 8%, which to help treat any infection. Zinc oxide in the amount of 8-20% also is taught as an additional base. Aloe vera may be included in the amount of 0.01-0.05% for sever skin problems.

Oliver teaches a composition water, 20% glycerin (humectant), 18% calamine (ferric oxide and 0.5% zinc oxide), 18% zinc oxide, 5% witch hazel (flavonoids-polyphenols), 0.88% ascorbic acid, 5% EDTH, 5% peroxide, 2% golden seal (flavonoids-polyphenols), 0.70% tea tree oil (terpenes), and 0.16% vitamin E.

Oliver does not teach an amino acid in the composition. Further, Oliver does not teach a polyunsaturated fatty acid.

Horrobin et al teach a topical pharmaceutical composition containing for the treatment of lesions causes by allergic reactions, insect bites, wounds, and the composition provides a soothing effect. See column 4, lines 10-25. The composition comprises lysine in the amount of 0.01-20% for the treatment of lesions (column 1, lines 53-55; zinc salts 0.01-10% for the

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bioconversion of linoleic acid and its own healing properties (column 5, lines 3-14); rutin which comprises bioflavonoids for blocking prostaglandin synthesis; and linoleic acid from vegetable oils for treating skin inflammation (column 2, lines 30). Horrobin teaches the use of rutin for an anti-inflammatory affect (a flavonoid, which is classified as a polyphenol) in the amount of 0.01-20%.

Di Paoli teach a composition that is applied to intact or injured skin. See column 1, lines 5-20. The composition comprises vitamins in the amount of 0.01-10%, amino acids (alanine arginine, aspartic acid, asparagine, cysteine, glutamic acid, glutamine, glycine, histidine, leucine, isoleucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, or valine) in the amount of .001-20%; chemical substances from plants, including triterpenes, saponins, isoflavonoids, alcohol flavonoids including anthocyanidins (flavonoids-polyphenols). The anthocyanidins include quercetin, isoquercetin, echinacosides (from Echinacea), echinacin in the amount of 0.01-20%, the plant extract itself including echinacia, witch hazel, and combinations, in the amount of 0.01-30% or 0.25-20%. See column 4, line 30-65 to column 5, line 5. The composition is used to treat acne, increase circulation, dermatitides, heal wounds, etc. see column 5, lines 20-35.

First, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oliver and Horrobin et al and further utilize lysine and polyunsaturated fatty acids in Oliver's composition. One would have been motivated to do so since Horrobin teaches lysine treats lesions of the skin and polyunsaturated fatty acids provide an anti-inflammatory effect. Therefore, a skilled artisan would have been motivated to additionally add a polyunsaturated fatty acid for its additive effect of treating skin inflammation

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and utilize lysine in treating skin lesions caused by the allergic reactions, bites, and acne.

Further, a skilled artisan would have been motivated to combine the teaching with a reasonable expectation of success since both references teach the treatment of skin rashes and inflammation and to provide a soothing effect. Therefore, "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Second, as evidenced by Hwang et al and Wikipedia, Goldenseal, Witch Hazel, and Echinacea all contain polyphenols including flavonoids (quercetin, echinacosides, rutin). Note that flavonoids are species within the genus polyphenols. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Di Paoli and utilize either the natural plant extract or the chemical active in the plant extracts such as flavonoids to treat skin conditions such as acne. Thus, it is within the skill to utilize the plant extract or the active chemical constituent itself in the instant amount to treat skin conditions. Further Di Paoli teaches the use of the plant extract or the active chemical constituents in the instant amount wherein this amount overlaps the amount taught by Oliver. Therefore, it is within the skill of an artisan to manipulate the concentration to achieve the optimal benefit. It is also noted that Horrobin teaches the use of rutin in the amount of 0.01-20%, which is a chemical constituent of Echinacea.

Regarding the recitation at least one trace element, note that calamine contains ferric oxide.

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Regarding the recitation at least one vitamin, Oliver teaches the incorporation of vitamins and Vitamin E is used in the composition.

Regarding the recitation at least humectant, Oliver's composition comprises glycerin.

Regarding the recitation at least one antifungal or antimicrobial components, Oliver teaches the incorporation of tea tree oil.

**Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (5,962,517) in view of Oliver (5,869,062) in view of Horrobin (5,145,686) or EP 0281812 respectively, in view of De Paoli (6,147,054) as evidenced by Hwang et al (Antimicrobial constituents from goldenseal (the Rhizomes of Hydrastis canadensis) against selected oral pathogens, Planta Med. 2003 Jul; 69(7):623-7); Wikipedia-Echinacea; Wikipedia-Witch Hazel; and [http://www.globalherbalsupplies.com/herb\\_information/aloe\\_vera.htm](http://www.globalherbalsupplies.com/herb_information/aloe_vera.htm), in further view of Burke et al (5,693,318).**

The disclosure of Oliver, Horrobin, EP'812, and Di Paolo have been set forth above. As noted in the discussion of Oliver, Oliver teaches the use of peroxide such as hydrogen peroxide in the composition to treat infection.

The combined references do not teach the instant peroxides claimed.

Burke teaches keratolytic agent such as salicylic acid and peroxide compounds which acts as an antiseptic for disinfecting the skin. See abstract and column 1, lines 15-30. Burke teaches peroxides useful include hydrogen peroxide, zinc peroxide, sodium peroxide. The peroxides are used at a preferred level of 0.5 to 5% by weight, a more preferred level of 0.5 to 3% by weight and a most preferred level of 1 to 2% by weight. See column 5, lines 35-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute hydrogen peroxide with the instantly claimed peroxides. One would have been motivated to do so with the reasonable expectation of similar results since Burke teaches hydrogen peroxide and the instantly claimed peroxides all function as disinfectants and may be used topically to treat the skin. Therefore, it prima facie obvious to substitute one equivalent component for another equivalent with the expectation of similar results since the art clearly establishes functional equivalency, i.e. the pharmacological property of acting as a disinfectant when topically applied.

**Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver (5,869,062) in view of Oliver (5,869,062) in view of Horrobin (5,145,686) or EP 0281812 respectively, in view of De Paoli (6,147,054) as evidenced by Hwang et al (Antimicrobial constituents from goldenseal (the Rhizomes of *Hydrastis canadensis*) against selected oral pathogens, *Planta Med.* 2003 Jul; 69(7):623-7) Wikipedia-Echinacea; Wikipedia-Witch Hazel; and [http://www.globalherbalsupplies.com/herb\\_information/aloe\\_vera.htm](http://www.globalherbalsupplies.com/herb_information/aloe_vera.htm), in further view of Squires (6,335,684).**

The disclosure of Oliver, Horrobin, EP'812, and Di Paolo have been set forth above. IN particular, Oliver teaches the use of Echinacea.

Although Oliver suggests the composition for skin infections, Oliver does not specify cellulitis.

Squires teaches the use of an antimicrobial concentrate comprising Echinacea phytochemicals such as echinacoside and cichoric acid, which are classified as polyphenols. The composition is useful against various microbial infections and can be used to inhibit bacterial

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diseases such as cellulitis. See column 2, lines 45-55 and column 3, lines 5-20. Echinacoside is preferably contained in an amount of 0.3-9% echinacoside. See column 6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and expect the composition to treat cellulitis. One would have been motivated to utilize the composition to treat cellulitis and reasonably expect success since Squires teaches the phytochemicals in Echinacea, which are taught by Oliver, treat microbial infections including cellulitis.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/  
Primary Examiner, Art Unit 1611